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WP2 STUDY AND ANALYSIS
D2.1 GOVERNANCE OF PANDEMICS AND EPIDEMICS

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Action plan on SiS related issues in Epidemics And Total Pandemics

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EXECUTIVE SUMMARY

This report reviews the issue of governance of pandemics and epidemics from three interrelated perspectives. Each perspective involves a different stakeholder which participates in the process of risk communication, and performs its own role. International public health cooperation is essential to mitigate the spread of epidemics. Therefore, these stakeholders need to collaborate and communicate with the others in order to identify a pandemic, stop its spreading and prevent it.

The first part of this report reviews the role and performance of World Health Organization (WHO) during the 2009 H1N1 pandemic. This organization had revised the International Health Regulations (IHR, 2005) and has strengthened its position as a central global force with authority and accountability in the field of international health. We investigated the eight core capacities defined by the IHR, and identify some gaps in the conceptual framework for monitoring these capacities. We also analyzed two case studies for compliance with the revised IHR in Israel and Ukraine.

The second part of this report turns its attention to a different stakeholder: The pharmaceutical industry and its performance in the process. Mainly, we targeted the issue of Conflict of Interests (CoI) between health authorities and pharmaceutical companies, and around the potential impact of those companies on the decision making process held by health authorities. Their influence ranges from providing finances to "The revolving door" phenomenon.

The last part of this report deals with the role of the media as the one who should have monitored governance performance during the 2009 H1N1 pandemic. We examined the communications that occurred between the media and two central health authorities: WHO and the Center for Disease Control and Prevention (CDC). Both authorities held virtual press conferences during the pandemic, so we could study the issues the journalists focused on and asked about: The declaration of the H1N1 influenza as such, the decision to hasten vaccines' production, and transparency of stakeholders' conduct in the decision making process and possible conflicts of interests.

1. THE INTERNATIONAL HEALTH REGULATIONS

The objectives of this task were to review the role and performance of the WHO, ECDC and CDC in the 2009 pandemic, focusing on published documents and press reports. Keeping this in mind, the 2009 H1N1 pandemic would be the departing point for this report, highlighting the lack of trust and perceived conflicts of interest that was emphasized by the WHO conduct.

The main question of this report would be how does the WHO achieve its global governance? To answer this question we will analyse relevant aspects of the revised IHR (2005). In order to tackle some of those questions, we briefly review the different transformations the IHR underwent until its current formulation (2005). We have reviewed the role and performance of WHO during the 2009 H1N1 pandemic in light of the revised IHR. Finally, we investigated the eight core capacities defined by the IHR. It is important to note that this document will serve as a basis for understanding the cooperation between WHO and Member States. In the second half of our report, we will focus on the communicational aspects of the collaboration between WHO and national agencies during the 2009 pandemic, through an Israeli and Ukraine case studies.

1.1. Background to the IHR

In 1951, the International Sanitary Regulations (ISR), were adopted by the World Health Organization and focused on six communicable diseases requiring coordinated international measures to control their transmission between countries. (Hardiman, 2012) Member countries have made use of the constitutional provision that permits the Health Assembly to adopt regulations concerning sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease (Tucker, 2005). In 1969, the ISR were renamed the International Health Regulations (IHR) (Hardiman & Wilder-Smith, 2007). The IHR are an international legal instrument that is binding on member states of WHO (essentially all countries in the world [Wernli et al., 2011]). Their aim is to help the international community prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide.

In 1995, it was decided that there was a need to revise the IHR. The revised IHR were adopted in 2005, and came into force in June 2007. Hardiman (2012) describes them as "a legally binding global framework to support national and international programs and activities aimed at preventing, protecting against, controlling, and providing a public health response to the international spread of disease". They deal with the actions to be taken during public health emergencies and strengthening of national public health infrastructure.

The new IHR (2005) covers a wide spectrum. This includes case definitions of diseases, the definition of a public health emergency of international concern (PHEIC), and the definition of public health risks. There is considerable emphasis on collaboration between organizations. At the country level, the IHR (2005) are supported by the designation of a national focal point (NFP). NFPs are national centers, and they play a central role in conducting the communications aspects of the IHR, both within the countries and internationally.

The mechanisms for advice and oversight of national capacity development include a number of components. These include a national roster of experts that can be called upon immediately to deal with any crisis, special emergency committees to manage the response to the crisis, review committees to monitor progress and review lessons learned from the event and global support through policy development at the World Health Assembly (WHA) and regional committees of the WHO (Andrus et al., 2010).

The IHR states that the member states need to strengthen the existing national structures and resources to meet their core capacity requirements with regard to surveillance, reporting, notification, verification, response and collaboration activities and activities at designated airports, ports and ground crossings (Katz et al., 2012; May, Chretien & Pavlin, 2009). At the local level, it is recommended that the capacities be expanded to detect events involving disease or death above expected levels for the particular time and place in all areas within the country, and to report all available essential information immediately to the public health authorities. At the community level, reporting shall be to local community health-care institutions or the appropriate health personnel. At the primary public health response level, reporting shall be to the intermediate or national response level, depending on organizational structures (MacDonald et al., 2011). The essential information includes clinical data, laboratory results, sources and type of risk, numbers of human cases and deaths, conditions affecting the spread of the disease and the health measures employed.

At the intermediate public health response levels the capacities need to confirm the status of reported events and to support or implement additional control measures, assess reported events immediately and, if found urgent, to report all essential information to the national level. The criteria for urgent events include serious public health impact and/or unusual or unexpected nature with high potential for spread. This is particularly important for suitable risk communication to the public (Hollmeyer et al., 2012). It is recommended that the capacities should include the ability to assess all reports of urgent events within 48 hours and notify WHO immediately through the IHR National Focal Point.

Public health response capacities should include measures to rapidly implement control measures required to prevent domestic and international spread. This includes specialized staff, laboratory analysis of samples, logistical assistance and on-site assistance for local investigations. There should be direct communication between senior health authorities for implementing control measures, and direct liaison with other relevant government ministries. Communication should include hospitals, clinics, airports, ports, ground crossings, laboratories and other key operational areas. Clear procedures should be in place for the dissemination of information and recommendations received from WHO.

As regards influenza pandemics, the revised IHR (2005) regulates the WHO as an organization that serves as a coordinating center at two levels. On the first level, WHO addresses questions of efficient global monitoring of the pandemic. On the second level, WHO serves as a communication center which simultaneously creates global messages and serves as a relay station which receives, examines and validates information. In order to fully understand WHO's role in light of the new IHR regulations, one must focus on the main revisions the document underwent at both levels. Thus, we emphasize the main differences between the revised IHR (2005) and its former versions in order to highlight WHO's new defined role.

Subsequently, we will not only discuss the formal legal authority IHR grants WHO but also its de facto function during the H1N1 pandemic of 2009.

1.2. The Revised IHR and Core Capacities

The eight core capacities represent the ability and the will of WHO and the Member States to comply with the revised IHR 2005 (Hollmeyer et al., 2012). It seems that achieving these capacities is an essential global objective, but also it is an opportunity to examine our progress towards our mutual goal and, most importantly, it is a chance to raise questions in order to improve the IHR's implementation (Andraghetti from PAHO/ WHO).

1.2.1. National Legislation, Policy and Financing

The first Core Capacity deals with State Parties having an adequate legal framework to support and enable implementation of all their obligation and right. Some states would have to considerably modify their legislation to support the spirit of the revised IHR. New legislations, regulations and other instruments should facilitate coordination among different stakeholders and encourage the advancement of other Core Capacities.

Martin et al., (2010) investigated the extent to which laws across Europe support or constrain pandemic preparedness planning (2010). The results demonstrate wide differences across Europe in the

extent to which national pandemic policy and pandemic plans have been integrated with public health laws. There seem to be significant differences in "legislation and by law, the extent to which borders could be closed to movement of persons and goods during a pandemic and access to healthcare of non-resident persons" (Martin et al., 2010). This can have harsh consequences on planning and preparations on all levels (Kim et al., 2012). Moreover, the revised IHR (2005) holds special challenge for federalist nations (Australia, Canada, Germany and India) because "it imparts national obligations onto what is traditionally a state and local function" (Katz & Kornblet, 2010; Wilson et al., 2008). In this case, the success of IHR (2005) rests upon the ability of these nations to find a balance between public health regulation in the authority of the local government opposing the authority of the national government (Wilson, von Tigerstrom & McDougall, 2008).

The first question that arises on the subject of policy and financing is whether the WHO can establish a situation in which there is an equality of burden among the member states. While trying to establish this formula one must keep in mind that some countries' burden is much heavier than other's. Namely, the distribution of financing must be as equal as possible but also take into an account the limited abilities some of the countries are faced with. While developed countries take for granted sanitation, hospitals and professional doctors, resource limited countries sometimes have to make hard cuts in order to face WHO's minimum requirements. However, in the global age surveillance problems thousands of miles away, become very quickly our surveillance problem. If pandemics won't be contained at the area of their outbreak they will travel to our doorstep. Hence, the question should be not whether developed countries should help resource limited countries, but how they can help (or to what extent). The bottom line is that efficient global surveillance is a shared interest of all member countries (McNabb, 2010).

1.2.2. Coordination and NFP Communications

"To establish effective communication channels, the IHR (2005) request each member state to designate a National Focal Point and WHO to designate IHR Contact Points at its headquarters or regional offices as operational links for urgent communication concerning the implementation of the IHR (2005)" (Oshitani et al., 2005). It can be argued that National Focal Points (NFPs) reflect the commitment member states have towards the IHR (2005). A successful establishment of NFPs indicates an intention for global cooperation and communication with WHO and other member states. Thus, it is not surprising that the majority of member states successfully established NFPs. As Hardiman notes, "NFPs are national centers, not individual persons, that occupy a critical role in conducting the communication aspects of the IHR, within their countries and internationally" (2012). These centers have a number of tasks, of which the most important ones are to distribute information that comes from WHO to the relevant domestic agents, to report to WHO about any

health regarding related information that can bear relevance on a global level and to provide WHO with feedback about the national preparedness in case of an outbreak and, with WHO's coordination, to ameliorate national capacity. Furthermore, the local NFPs can serve as a pipeline between WHO and the local audience, helping to understand and communicate public opinion.

However, not all NFPs work according to the standard which goes along with the spirit of the revised IHR (2005). To improve these NFP's activity, WHO initiates courses and workshops on which we will elaborate in the human resources section. It is import to note that after the 2009 N1H1 influenza there have been raised some critiques against the level of collaboration between WHO and some NFPs. Low et al., illustrate this notion through the Singaporean example (2011). The claim is that while the Singaporean NFP provided WHO with timely information, the IHR NFPs were not responsive. This lack of information led Singapore NFP to explore alternative sources of information which obviously should not happen in times of a severe outbreak. It seems that these sorts of discrepancies should be resolved immediately in order to establish a more efficient and valid way to communicate during crisis.

1.2.3. Surveillance

One of the most important core capacities that are yet to be fully achieved is improving surveillance, and in some cases establishing a surveillance system, in resource limited countries. Obviously, it is not always merely a technological question and, in fact, the 'heart' of every good surveillance system is communication. "It is the speed of communication which is most critical to contain or stamp out an outbreak, save lives and prevent misery" (Kant & Krishnan, 2010) Although a variety of surveillance systems have been established around the world it seems there are still a lot of technological gaps between developed countries and resource limited countries (Campbell et al., 2012). As Quandelacy et al. (2011), note "many resource-limited countries still lack access to appropriate electronic surveillance systems, which may limit their ability to rapidly detect outbreaks and other health events that affect resource poor countries and the international community. Apparently, the assessment shows that IHR 2005 "constitutes a major advance in global surveillance from what has prevailed in the past" (Baker & Fidler, 2006).

In this aspect, WHO's agenda should focus on reduction of gaps between different countries. Thus, the ultimate goal of all member states should be one - to establish an efficient global surveillance system. Obviously, this cannot be achieved without the participation of every state in this effort. From this aspect, "chains of responsibility need to be clearly identified to ensure effective communications within the country, with WHO and with other countries as needed" (WHO website).

1.2.4. Response

The main question that incorporates different issues regarding response to pandemic outbreak deals with the aggresiveness of WHO and member state's reaction. Namely, how do we act? What is the critical mass for declaring an outbreak? How we alert the public without arousing panic. It is important to note that, in the aftermath of 2009 H1N1 influenza, one of the voices against WHO's response made the case that WHO overestimated the severity of the outbreak resulting in a mass panic. However, it seems that in the early stages of an outbreak when solid and verified information is sparse it is better to exaggerate than to underestimate. This brings about the public health paradox; while "failure to move aggressively in the early stage of pandemic influenza can have catastrophic consequences, actions that prove to have been unnecessary will be viewed as draconian and based on hysteria" (Gostin, 2004). Along with Gostin (2004), who recommends it safe to claim that what should characterize a wise response is not only its severity but also its ethical code and considerations (2004).

1.2.5. Preparedness

Preparedness encompasses the achievement of a national response public health emergency plan. The discourse around the concept of preparedness focuses on different elements. First, we must consider preparedness on the global level, considering WHO, CDC and ECDC and all member states as a complex network that must achieve and maintain an open communicational channel in order to assess questions of surveillance and coordination (Azziz-Baumgartner et al., 2009). Moreover, we need to expand initiatives that include WHO's conferences, workshops and courses to help different agents to specialize in working together in WHO in light of IHR 2005. On the national level, we talk about two-way preparedness. Namely, working with regional agents in order to establish approved partnerships such as MECIDS and MBDS but also achieving a high preparedness level in communication with the public. Communication with the public should be based on risk communication; working with communication researchers in order to understand public opinion and assess the issues that are relevant for each specific sub-group. These tailored interventions should promote pro-health initiatives not merely in times of outbreaks but on a regular basis. Although it is not always completely understood what is the appropriate role of each agent in this network, "responding to infectious disease threats is every State's prerogative, and inter-State collaborations…are essential to secure global public health preparedness" (Bhattacharya, 2007).

1.2.6. Risk Communication

"Risk communications should be a multi level and multi faceted process which aims to help stakeholders define risks, identify hazards, assess vulnerabilities[11] and promote community resilience, thereby

promoting the capacity to cope with an unfolding public health emergency"(WHO website). In accordance with the lesson of SARS outbreak and the spirit of IHR 2005, WHO's determined position is that massive mass media campaigns should be used in order to decrease transmission, inform the population, promote hygiene (sick people should be monitored and health should keep distance). It is important to note that social media could potentially play a major role in these sorts of campaigns, helping the message get through not only via traditional channels but also through the new media. Even more important, Information should be communicated in a transparent, accurate and timely manner" (WHO global conference on SARS: where do we go from here? (Summary Report, Kuala Lumpur, 2003, in O'Malley, Rainford & Thompson, 2009). It seems that some of these lessons were implemented into risk communication during H1N1 2009 influenza outbreak. Following the Mexican Pandemic Plan, "a program of social mobilization was implemented through a multifaceted mass media saturation campaign featuring visual representations and a previously developed and tested message icon, "promi", to address Mexico City's heterogeneous population and literacy rates" (Bell et al., 2009).

Nevertheless, there are still some questions remained unanswered. If WHO is responsible for the messages produced and distributed during an outbreak, is it also include risk communication? If it is, what is the best platform to achieve effective results? Will the WHO be in any way responsible for distributing or monitoring messages that are being used for different interventions? Will such messages be homogeneous or will they be culturally tailored for different member states? What happens if a state does not agree with the message and wants to produce other messages? It is important to note that there is relatively very little research on the effectiveness of risk communication during times of crisis and this could very well be the missing link on the way to achieving better surveillance and faster containment.

1.2.7. Human Resources

Advancing the skills as abilities of public health professionals is crucial to the sustainment of public health surveillance and response. Furthermore, the "availability of human resources with the appropriate mix of knowledge, skills and competencies constitutes an essential requirement for Member States to fulfill their obligations" (WHO website). Accordingly, Member Parties should provide short term and long term work force learning plans and a broader strategy for the allocation of funds to train workforce.

1.2.8. Laboratory

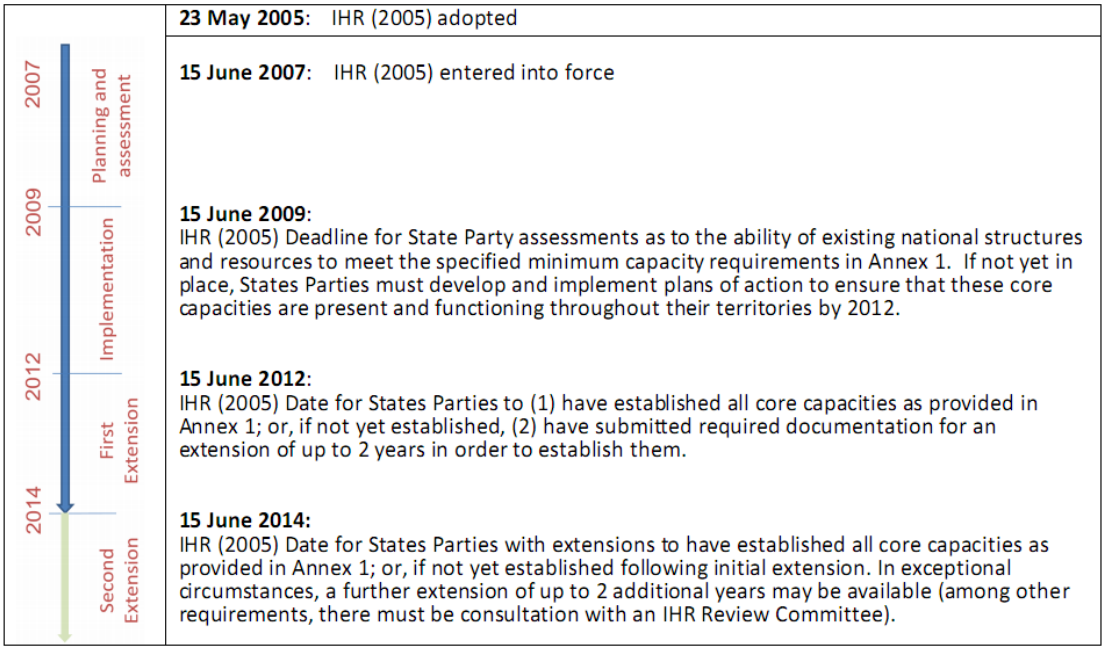
According to the declaration of the "World Health Assembly in 2005 that urged its member states to strengthen national laboratory capacity for human and zoonotic influenza" (Wetheim, 2010), it is self evident

that member states laboratories should strive for the highest standards (Najjar-Pellet, 2013). The objectives for the "laboratory strengthening program was to enhance laboratory facilities; ensure availability of necessary equipment; build human resource capacity by teaching, training and mentoring; and ensure quality laboratory management and testing" to comply with international standards (Wetheim, 2010).

The Tanzania Field Epidemiology and Laboratory Training Program (TFELTP) serves as a good example of cooperation on the national and international levels that can bring about change and establish laboratory capacities that correspond with the IHR 2005. Although the program is not perfect and there is still room for improving "in-country teaching capacity for the program, as well as a career path for graduates" (Mmbuji, 2011), it shows that with relatively small economical investment countries can establish a surveillance system by upgrading their laboratory capabilities. Nevertheless, there is still more guidance needed to achieve the standard that the spirit of the revised IHR strives for.

1.3. IHR Monitoring Framework

With the implementation of the International Health Regulations (IHR) during 2007, all Member States were required to assess their ability on a national and sub-national level in order to meet the given core capacities and design an action plan to insure that their capacities could be further developed by 2012. The task of WHO as a global health regime was to guide and support the Member States in achieving their goals.



In order to provide specific guidance and directions to the Member States, the WHO have developed a monitoring framework for gradual implementation of the core capacities. Supposedly, this framework

represents the consensus of technical experts' views[1]. Namely, this framework consists of 28 global indicators for monitoring the development of IGR core capabilities and it serves as the operation definition of these capacities. Although Member States are encouraged to report annually on all 28 indicators, only 20 of them are requested annually by the Executive Board and the World Health Assembly (WHA).

1.3.1. Global Indicators

The following 20 indicators have been selected for reporting to WHA:

1. Legislation, laws, regulations, administrative requirements, policies or other government instruments in place are sufficient for implementation of IHR.
2. A mechanism is established for the coordination of relevant sectors in the implementation of the IHR.
3. IHR NFP functions and operations are in place as defined by the IHR (2005).
4. Indicator-based surveillance includes an early warning function for the early detection of a public health event.
5. Event-based surveillance is established.
6. Public health emergency response mechanisms are established.
7. Infection prevention and control (IPC) is established at national and hospital levels.
8. A Multi-hazard National Public Health Emergency Preparedness and Response Plan is developed.
9. Priority public health risks and resources are mapped.
10. Mechanisms for effective risk communication during a public health emergency are established.
11. Human resources are available to implement IHR core capacity requirements.
12. Laboratory services are available to test for priority health threats.
13. Laboratory biosafety and laboratory biosecurity (biorisk management) practices are in place.
14. General obligations at PoE are fulfilled.
15. Effective surveillance and other routine capacities are established at PoE.
16. Effective response at PoE is established.
17. Mechanisms for detecting and responding to zoonoses and potential zoonoses are established.
18. Mechanisms are established for detecting and responding to foodborne disease and food contamination.
19. Mechanisms are established for the detection, alert and response to chemical emergencies.

[1] IHR Monitoring Framework: Checklist and Indicators for Monitoring Progress in the Implementation of IHR Core Capacities in States Parties

20. Mechanisms are established for detecting and responding to radiological and nuclear emergencies.

1.3.2. Development of the Global Indicators Questionnaire

First of all, it is important to note that this monitoring tool was not intended for relative comparison between countries or regions but rather as a guide that helps Member States to acknowledge gaps and mitigate them. In developing the indicators the following six criteria were applied:

1. The global indicators must be based upon the revised IHR and correspond to the problems that Member States can potentially deal with.
2. The global indictors must encompass of the content of the core capacities and reflect system establishment at the national, intermediate and peripheral levels.
3. The scope of the questionnaire must relate to all relevant hazards (biological, chemical, radiological and nuclear).
4. The indicators must assess the quality of adherence and measures applied by Member States.
5. The timeliness of application of functions and services.
6. The documentation and dissemination of practices.

1.3.3. The Monitoring Checklist

This section demonstrates the organization of the monitoring checklist which encompasses the framework involved in the assessment of implementation of the core capacities through the global indicators, developed for the IHR. The checklist (see Fig. 1) includes the specific components of the core IHR capacity, the recommendation regarding the developing of the capacity, specific indicators related to the component, and the attributes of each indicator presented as level of capability.

Component of core Capacity	Country level Indicator	Current status of development of core capacities			
		<1 Foundational	1 Input and process	2 Output and outcome	3 Additional achievements
		Attribute	Attribute Attribute Attribute	Attribute Attribute	Attribute

Figure1 - Monitoring Checklist for the IHR core capacities

Component of core capacity

This section relates to the eight core capacities of the IHR 2005, which reflect the operational meaning of the capacities required to detect, assess, notify and report events, and to respond to public health risks and

emergencies of national and international concern. To strengthen Member States capacities, a set of components are measured and reported.

Country level indicator

For each component a set of one-three are assessed to evaluate the current status and progress in developing and strengthening the IHR core capacities

Attributes

The attributes are specific questions which measure and assess a country level indicator. Therefore, each indicator is assessed by using a group of attributes. One to three questions are derived from each attribute and these are reported through a questionnaire.

1.3.4. Capability Level (of an Attribute)

Each attribute is assigned a capability level or a "level of maturity". The direct meaning of the capability level is that a given capability level requires that all attributes at lower levels are in place. In this form, there are four capability levels:

- **Level < 1** is the absolute foundation, hence there are several critical attributes requires proceeding to the next level of capability.
- **Level 1** a moderate level of functioning and preparedness. It usually implies that the required abilities are at least present.
- **Level 2** is a strong level of a functioning attribute, suggesting a transition from intentions to outcomes.
- **Level 3** reflects an advanced process of reassessment whereby lessons learnt from past experience are evaluated, documented and shared on a national and international level.

1.3.5. Capability Level (of an Indicator)

The capability level of an indicator is based on all of its attribute levels. An indicator is considered achieved only if all the attributes within that indicator are achieved (see Fig. 2). For any indicator, the level is:

Level < 1 if no attribute is achieved.

Level 1 if at least one Level < 1 and one Level 1 attribute are achieved.

Level 2 if all Level 1 attributes and at least one Level 2 attribute are achieved.

Level 3 if all Level 1 and Level 2 attributes, and at least one Level 3 attributes are achieved.

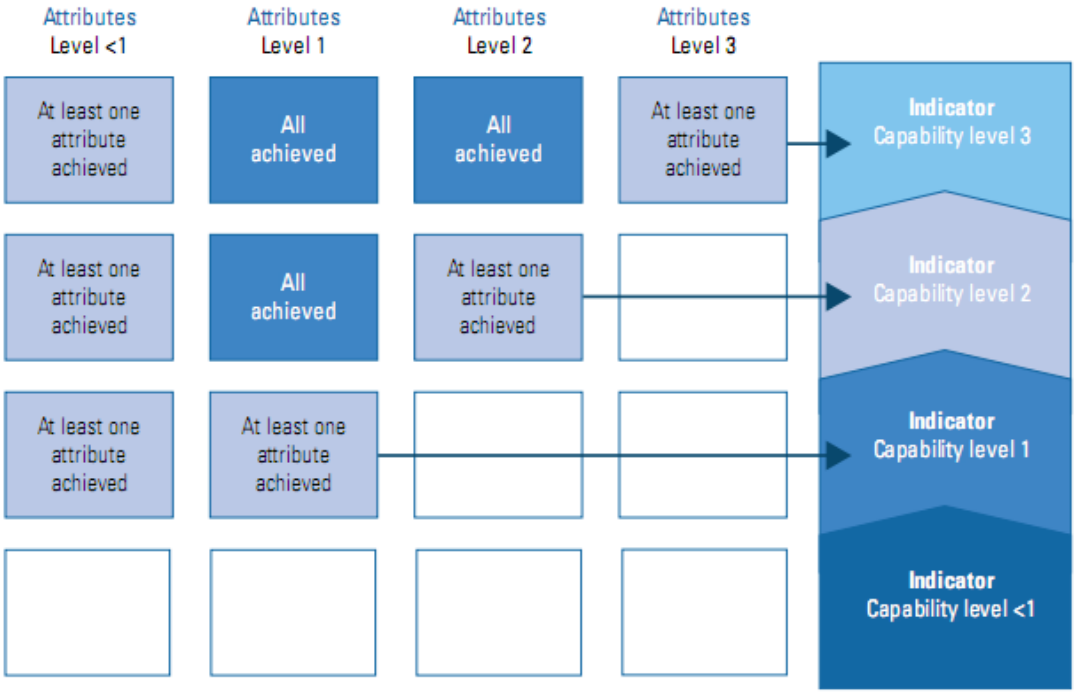


Figure 2- Capability level of an indicator

1.3.6. Capability Level (of a Core Capacity)

The capability level of a component is the same as that of the indicator under this component, as there is a one-to-one relationship between a component and an indicator. Importantly, the Capability Level of a Core Capacity is determined by the lowest indicator level of all indicators under this Core Capacity (for example see Fig. 3).

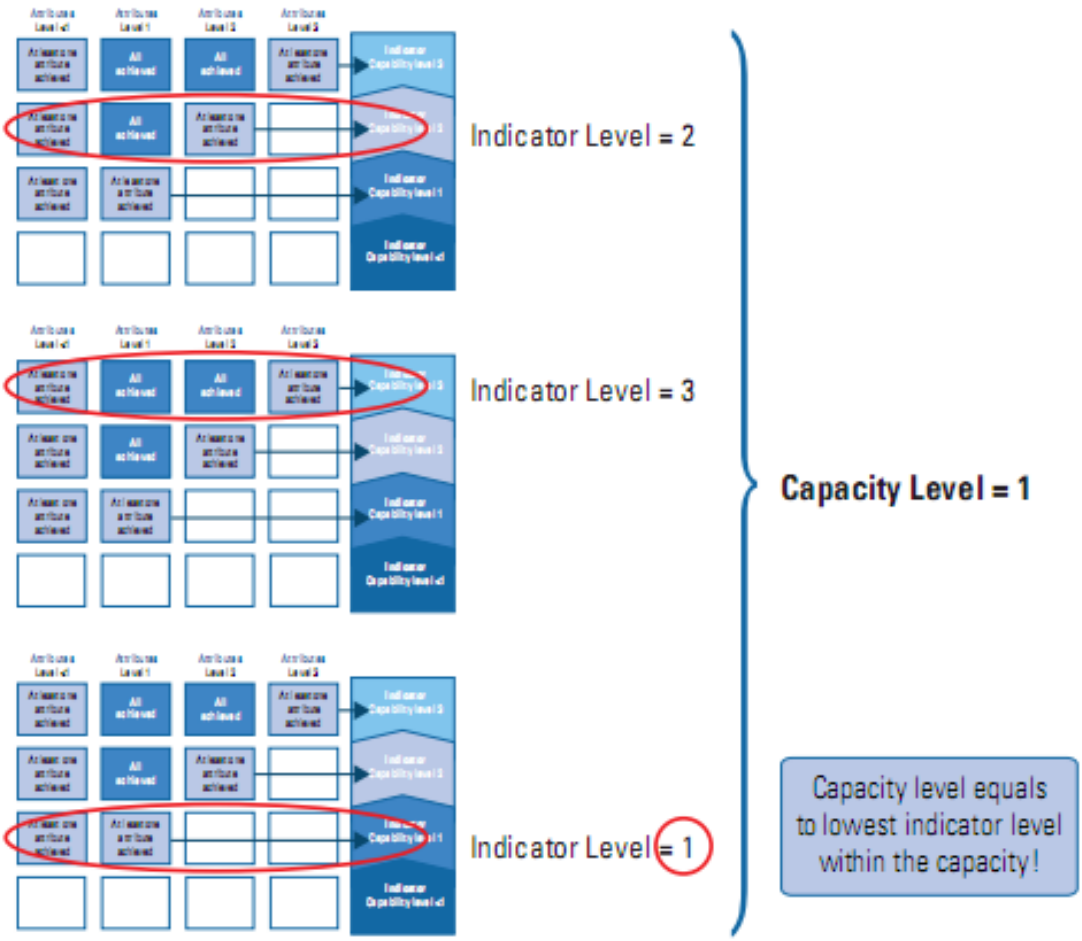


Figure 3- Capability Level of a Core Capacity

1.3.7. The Attribute Score

This score stands from the documented progress made towards the attainment of a core capacity. The scores ranging from 0 to 100% are calculated using an internet-based tool. According to the last update, in calculating the attribute score, the numerator is the total number of attributed achieved in Level 1 and 2, and the denominator is the sum of Level 1 and 2 attributes.

Table 1 shows the main differences between the 2009 and the current version of the States Parties Reports

Area of Change	States Parties Report 2008/2009	States Parties Report 2011
Number of Sections	1. National IHR Focal Point (NFP), 2. National Legislation and Policy 3. PoE 4. National core capacities in surveillance and response 5. Financial resource gaps 6. National legislation, regulations and administrative requirements for implementation of the IHR 7. Participation in relevant international arrangements 8. Structured to take into account all core capacities and hazards	1. Legislation and Policy 2. IHR coordination 3. Surveillance 4. Response 5. Preparedness 6. Risk Communications 7. Human Resources 8. Laboratory 9. POE 10. Hazards ▪ 10.1. Zoonotic ▪ 10.2. Food safety ▪ 10.3. Chemical emergencies ▪ 10.4. Radiological emergencies
Scope	Less emphasis on major IHR relevant hazards (chemical, radiological, zoonotic, and food safety)	Greater emphasis on need for consultation with relevant sectors/hazards and levels to reflect comprehensive capacity of Member States
Purpose of data collection	Data collection only for reporting to WHA	Data is collected primarily to assist the country in monitoring their status with respect to IHR capacities. A secondary purpose is to allow WHO secretariat to identify technical areas requiring support at country, regional or global levels. Finally a subset of the data collected will provide a means for the WHA to monitor progress in country implementation of the IHR in the area of core capacities.

1.4. Data Collection

One of the interesting aspects behind the implementation of the revised IHR 2005 has to do with the process of collecting data regarding the progress on achieving the core capacities. While the WHO leaves the final decision to the Member Parties, the recommendation is to establish a facilitating group of experts for developing different aspects of the core capacities. This group should work closely with the local NFP that, in turn, gives a progress assessment to the WHO. Another recommendation is to conduct frequent workshop (or round tables), together with various stakeholders in order to discuss gaps and ways to address them.

1.4.1. IHR Core Capacity Monitoring Workshop

While workshops are mandatory and their scope should be decided by national actors, WHO have suggested a programme that could bring some structure and unity to these meetings. According to WHO's outline the purpose of such a workshop is to;

- Update on IHR implementation, including the development of core capacities;
- Introduce the paper based and internet based tools monitoring progress;
- Identify strengths, gaps, opportunities and threats;
- Make recommendations on addressing gaps identified in strengthening core capacities.

Interestingly, the target audience of such workshop ranges from representatives of the NFP and major stakeholders to informal local representatives. These diverse teams seem to suggest that the compliance with the IHR occurs on various levels and it is not an exclusive task of the national healthcare authorities. The workshops consist of plenary sessions and group work. At the end of the workshop, participants are expected to complete the paper based or internet based monitoring checklist.

1.5. Member Parties compliance with the IHR Core Capacities strengthening process

One of the most important indicators of the ability of the WHO to become an international health regime is its ability to enforce their regulation. Simply put, the compliance of Member Parties with the revised IHR gives a good understanding about the WHO's governance. This report will focus on data from 2011, as it is the last data available online regarding Member States compliance. In 2011, 161 State Parties completed the Core Capacities questionnaire (about 83% of the 194 states). Figure 4 demonstrates the quantity of submitted versus not submitted questionnaires by WHO region of governance. Though in some regions the amount of not submitted reports is considerable suggesting a difficulty to comply with the IHR, it is important to note that between 2010 and 2011, the overall questionnaire submission rate increased from 65% to 83%. Nevertheless, it is noteworthy to mention that the submission rates from the Western Pacific region and the Eastern Mediterranean region have dropped slightly in 2011.

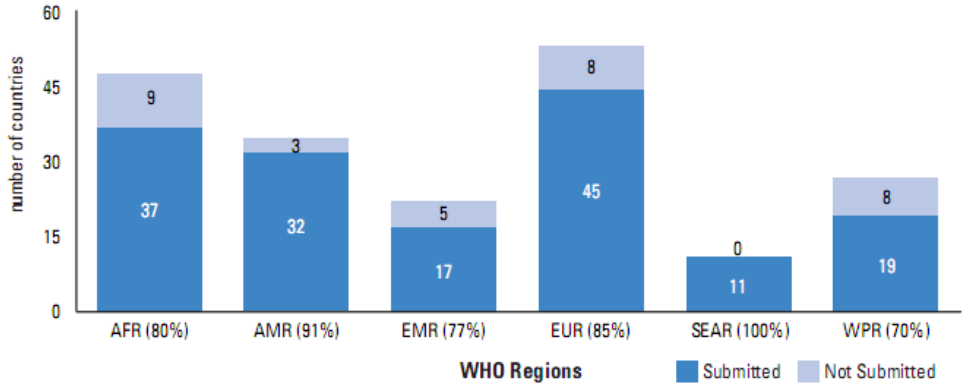


Figure4 - Questionnaire submission in 2011

When looking at specific capacities at a global level, it seems that State Parties are making good progress notably with regard to surveillance, response and laboratory service. Figure 5 represents an impressive progress in all eight capacities, however this data which deals with the global level seem to miss the whole story. According to the regional average scores for IHR core capacities, some regions are less than successful in advancing their IHR capacities.

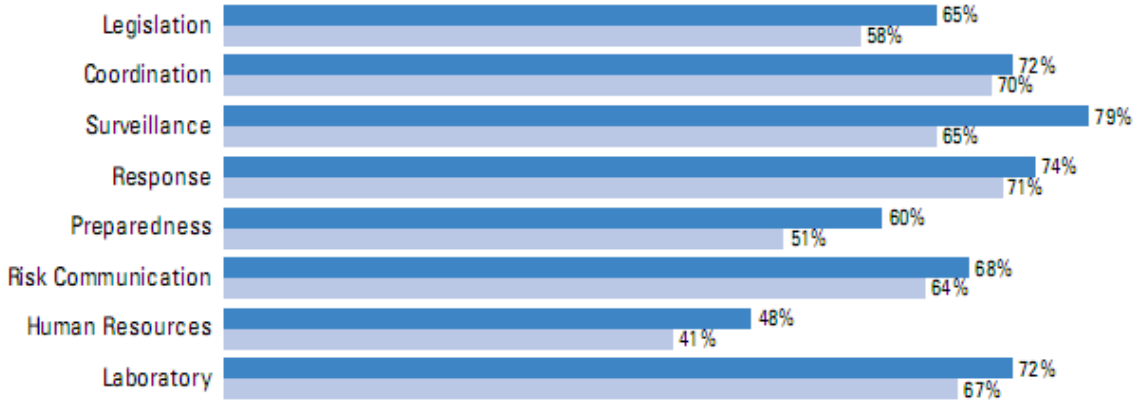


Figure 5- Global IHR core capacities, 2010 and 2011

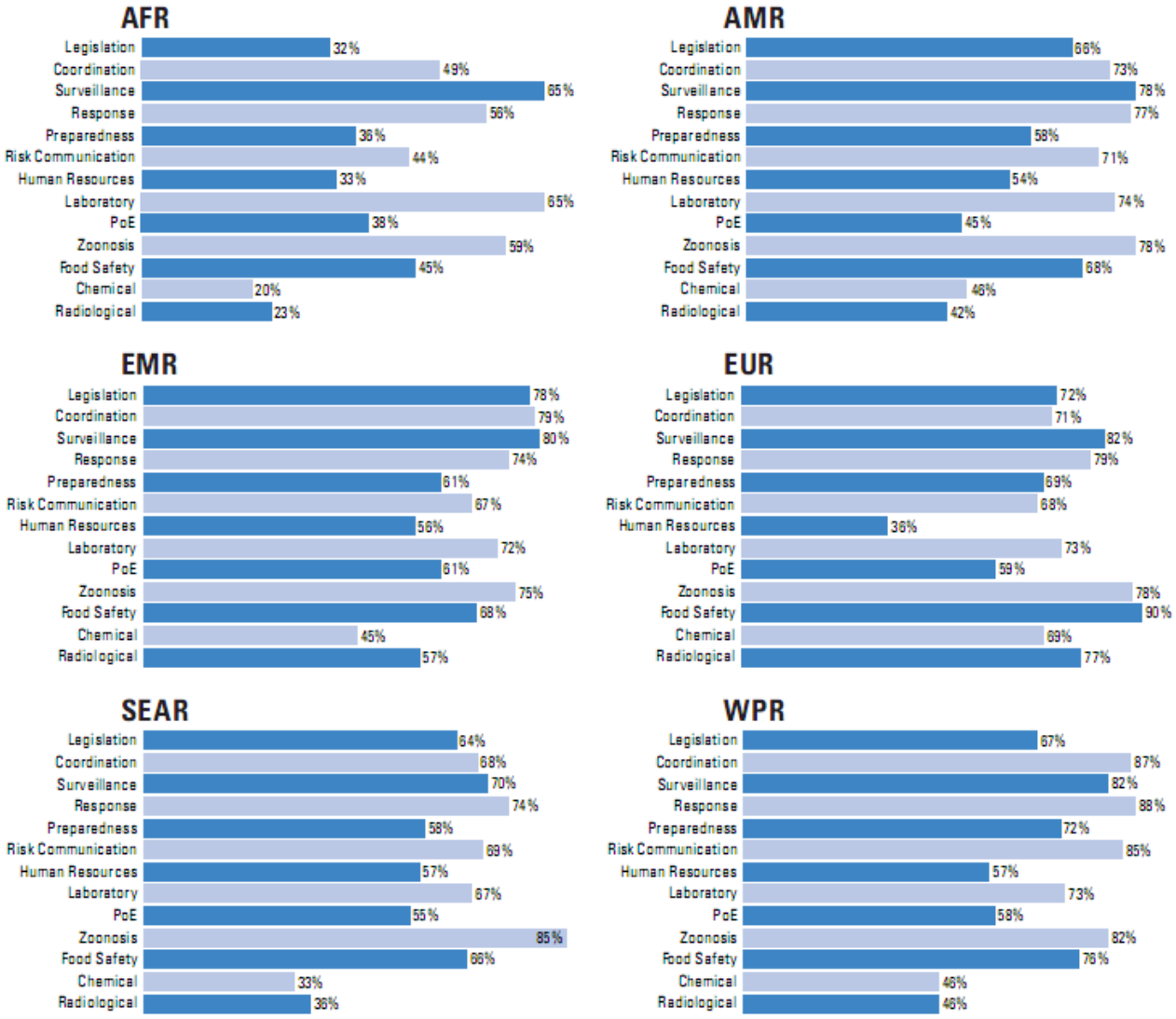


Figure 6- Regional average scores for IHR core capacities for 2011

At regional level, AFR countries achieved their highest scores in surveillance and laboratory capabilities (65%) but there is an evident necessity to achieve better capacities of preparedness and human resources (<38%) . EMR region is characterised by a successful progress in legislation, coordination, surveillance and response (>74%) but a deficiency in preparedness and human resources (<61%). This pattern is also true to SEAR and AMR countries. In other words, in these regions, Core Capacities such as legislation, surveillance, coordination and response are successfully advanced, while preparedness and human resources are under developed (<59%, 58%, respectively). Although the situation is considerably better in EUR and WPR regions, the broad gap between human resources and other capacities is alarming. For example in EUR human resources capacity is less than satisfactory with only 38% while other capacities are overall in a much better state. A similar gap is also evident in the data regarding capacities achievement in WPR region, when human resources remain undeveloped (57%), compared to other Core22Capacities (>66%).

It seems that the regional average scores for IHR Core Capacities suggest that the ability to achieve successful implementation of the IHR has to do with wealth and resources, where EUR region progress is evident compared to other regions. The first question that rises on the subject of policy and financing is whether the WHO can establish a situation in which there is an equality of burden among the Member Parties. While trying to establish this formula one must keep in mind that some country's burden is much heavier than others'.

Namely, the distribution of financing must be as equal as possible but also take into an account the limited abilities some of the countries are facing with. While developed countries take of granted sanitation, hospitals and professional doctors, source limited countries sometimes have to make hard cuts in order to face WHO's minimum requirements. However, in the global age healthcare problems thousands of miles away, become very quickly our surveillance problem. If pandemics won't be contained at the area of their outbreak they will travel to our doorstep. Hence, the question should be not whether developed countries should help limited resources countries but how they can help (or to what extent). The bottom line is that efficient global surveillance is a shared interest of all member countries (McNabb, 2010).

Another alarming aspect is the fact that in all regions the most undeveloped capacity is human resources. This is specifically problematic due to the fact that staff shortages sometimes prove to be a significant cause for surveillance shortfalls (Chretien, 2010). This equation becomes much more significant when we are speaking about third world countries, where training and qualification of experts and medical staff sometimes falls short. It is important to note that a great deal of the training focuses not only on medical training but also on communicational training thus opening a channel of communication can sometimes contribute to efficient surveillance just as good medical experts.

Considering the human resources capability deficiency, WHO has implemented several steps in order to achieved progress. The main focus areas are human resources development and training plans, providing guidance to Member States to establish a strategic approach to the development of human resources. IHR learning environment is another objective where WHO provides a framework in support of Member States. The third focus area is the development of IHR generic curricula and training materials. Finally, WHO has supported the design and development of specialised IHR learning program and activities, providing support on the analysis of needs, facilitation and evaluation of training.

More recent data regarding the status of country reports to WHO on implementation of Core Capacities seems to be a source for cautious optimism (Fig.7). While only 21% of Core Capacities are fully implemented and 64% are reported as "not implemented", 57% (of the 64%) have presented a detailed implementation plan that potentially should ameliorate the situation by the 2 year extension (2015).

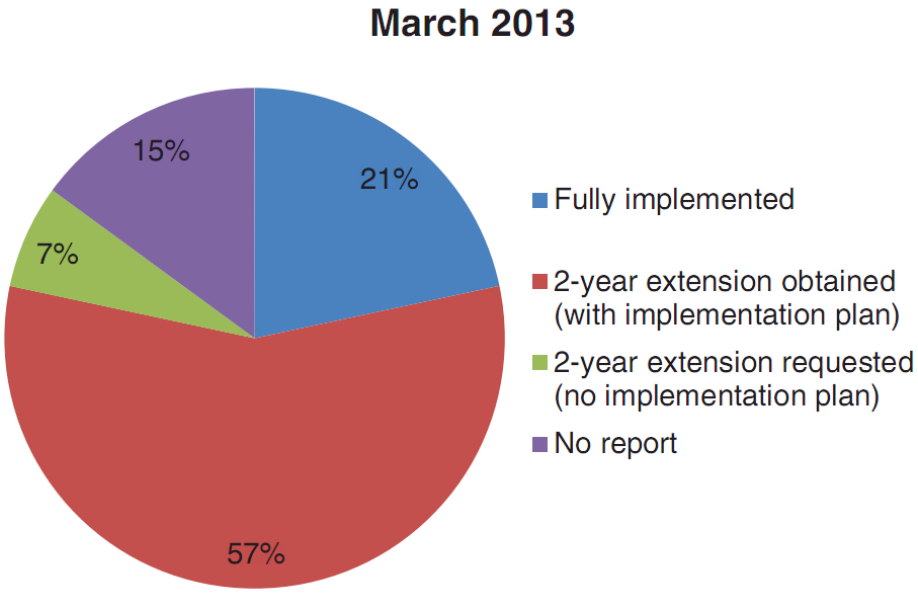
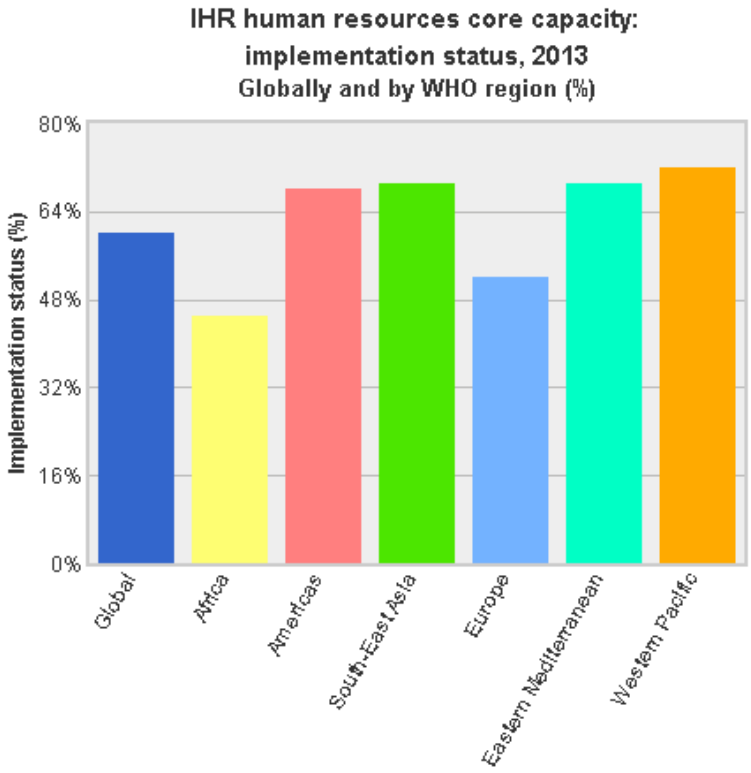


Figure 7- Status of country reports to WHO on implementation of IHR (2005)



2. CONFLICT OF INTERESTS

"A profit-driven industry does not invest in products for markets that cannot pay", asserted the WHO Director General Margaret Chan on a speech she gave at a conference in the West African country of Benin, in the midst of the Ebola crisis. Criticizing the pharmaceutical industry, Chan claimed that its drive for profit was one of the reasons the development of an Ebola vaccine was delayed. "two WHO arguments that have fallen on deaf ears for decades are now out there with consequences that all the world can see, every day, on prime-time TV news" (Gladstone, November 3, 2014). But while centering the blame on the industry, the WHO itself was criticized for its "collusive relations" with it, which was one of the problems that led, it was claimed, to the organization's inability to fight Ebola (The Japan Times, October 28, 2014). Brice de le Vingne, director of operations for *Doctors without Borders*, said that the WHO's state could be compared to a frog placed in a pot of water on a stove. "If you put a frog in cold water and start to heat it, she will not jump out of the pan, she will adapt to the temperature and she will not realize that she is boiling to death. WHO is the same" (Hussain, August 21, 2014).

The criticism around the WHO's conduct in the current Ebola epidemic reflects the growing concern regarding conflicts of interest (COIs) and "collusions" between health authorities and pharmaceutical companies, and around the potential influence of the pharmaceutical industry on the decisions made by health authorities (Flynn, 2010; Cohen & Carter, 2010; Godlee, 2010; Epstein, 2011). As Resnik (2004) points out, COIs can lead to biased research, injuries and low trust. But it can also lead to unbalanced allocation of budgets to diseases (Nozaki, 2013; Stuckler, King, Robinson, & McKee, 2008), and to flawed approval process of drugs and vaccines (DeLong, 2012; Cohen & Carter, 2010; Ferner, 2005). Perhaps the most prominent example of this concern is the 2009 H1N1 outbreak. In the aftermath of the H1N1 outbreak, there were significant concerns about competing interests among experts on influential advisory committees, including the WHO Emergency Committee (Flynn, 2010; Cohen & Carter, 2010; Epstein, 2011). Members of the WHO Emergency Committee have been linked to manufacturers of both neuraminidase inhibitors and influenza vaccines (Cohen & Carter, 2010; Epstein, 2011). "This was a pandemic that never really was", claimed Paul Flynn, a UK politician charged with investigating the handling of the H1N1outbreak for the Council of Europe (Macrae, June 4, 2010). On June 4, 2010, the *Council of Europe Parliamentary Assembly* published a harsh report (Flynn, 2010), claiming that the decision-making around the H1N1 crisis has been lacking in transparency, caused unjustified fear and prompted countries around the world to waste millions of dollars.

According to the report, "The parliamentary assembly is alarmed about the way in which the H1N1 influenza pandemic has been handled, not only by the WHO, but also by the competent health authorities at the level of the European Union and at national level. It is particularly troubled by some of the consequences of decisions taken and advice given leading to distortion of priorities of public health services across Europe, waste of large sums of public money, and also unjustified scares and fears about health risks faced by the European public at large".

Another report, a joint investigation by the BMJ and *the Bureau of Investigative Journalism* (Cohen & Carter, 2010) has uncovered evidence that raised troubling questions about how WHO managed competing interests among the scientists who advised its pandemic planning, and about the transparency of the science underlying its advice to governments. According to the report, the 2004 guidelines the WHO developed were based in part on the advice of experts who received consulting fees from the two leading manufacturers of antiviral drugs used against the virus, Roche and GlaxoSmithKline. Yet these COIs have never been publicly disclosed by WHO. "We are left wondering whether major public health organizations are able to effectively manage the conflicts of interest that are inherent in medical science", wrote Cohen & Carter (ibid, 2010: 1274). Their report detailed WHO's pandemic influenza preparation starting in 1999, when a preparedness plan was drafted by six researchers in collaboration with the European Scientific Working Group on Influenza (ESWI). According to the report, what that document didn't disclose, was the fact that ESWI is funded entirely by Roche, which makes the influenza antiviral Tamiflu (oseltamivir) – a drug the United States alone had stockpiled nearly US$1.5 billion dollars' worth of it Prior to the H1N1 outbreak in 2009 (Doshi, Jefferson & Del Mar, 2012), and other influenza drug manufacturers maker.

Furthermore, in the event leading to the 2009 pandemic, WHO did not reveal the identity of the 16 members of Emergency Committee whose role were to guide WHO on its policy regarding the beginning and end of the pandemic in 2009 (Flynn, 2010). This committee became secret to the public (Cohen & Carter, 2010).

2.1. Financial Relying on the Pharmaceutical Industry

A major issue standing in the center of the concerns around COIs is the authorities' heavy financial relying on the pharmaceutical industry. According to Shah (November 9, 2011), a group composed of business corporations including Coca-Cola Co and Pfizer Inc., is the world's top source of financing and leadership in the

fight against deadly disease. As the WHO, starved of public financing, is forced to rely upon voluntary contributions, these corporations' donations constitute today nearly 80 percent of the agency's budget.

Thus, they exert influence on the WHO's policies and decision-making and shape the global health agenda. The result is reflected in the agency's allocation of budgets to diseases. While its regular budget is allocated diseases that account for the most mortality around the world, most of the extra budgetary funds, that constitute the bulk of the WHO's overall expenditures, are spent on illnesses that account for a tiny fraction of global mortality (Shah, November 9, 2011). Diseases like malaria and tuberculosis, which together cause 2 million deaths a year, have received less attention from the WHO than high cholesterol (Suowiecki, 2014). According to Chirac & Torreele (2006), only 18 of the 1,556 new drugs that were developed between 1975 and 2004 were for neglected tropical diseases. This group of parasitic and bacterial diseases, such as Chagas disease and dengue, affects more than one billion people globally and kill an estimated 534,000 people worldwide every year (CDC, 2014).

Stuckler, King, Robinson & McKee M. (2008) reported that WHO budget allocations were heavily skewed towards control of infectious diseases. They concluded that WHO funding did not match the disease burden, particularly in the western Pacific region, which has low rates of infectious diseases and a high burden of non-communicable diseases by comparison with Africa. A reassessment of WHO's budgetary allocation done 5 years later yielded similar results. During 2008-13, WHO's budgetary allocations were still heavily skewed towards control of infectious diseases both in Africa, and in the western Pacific region (Nozaki, 2013).

Cols and industry funding could also result in industry influence on the approval process of drugs and vaccines (DeLong, 2012; Cohen & Carter, 2010; Ferner, 2005). Doshi (2013) claims that the studies underlying the policy promoting influenza vaccines – which is one of the most visible and aggressive public health policies today – are often of low quality, and do not substantiate officials' claims. According to DeLong (2012), this policy largely the result of the FDA's heavy reliance on the drug companies. The fees drug companies pay to the US FDA to have their drugs evaluated (In accordance with the Prescription Drug User Fee Act, adopted in 1992), she claims, can influence the approval decisions. Although the Act refers only to prescription drugs and not vaccines, since many vaccine manufacturers also produce prescription drugs, the user fees paid by them provide incentives for the FDA to be friendlier towards them (DeLong, 2012). Similarly, in the UK, a report released by the House of Commons health committee on "the influence of the pharmaceutical industry", described the substantial impact of this industry on health authorities (In: Ferner, 2005). According to the report, the annual

income of the Medicines and Healthcare Products Regulatory Agency (MHRA), which is the executive arm of the drugs Licensing Authority in the UK, stands at £65m, derived entirely from licensing fees.

The committee thought that the need to attract pharmaceutical business could conflict with the MHRA's duty to protect the public, and harm the thoroughness with which the MHRA reviews data submitted for licensing, as well as its ability, after licensing, to detect adverse drug reactions and act on them. Cohen & Carter's report on the pandemic planning (2010) refers to the chain of influenza drugs' approval in the FDA and the EMEA. In the US, the FDA advisory committee initially rejected zanamivir, another influenza antiviral drug, because it lacked efficacy. But the FDA leadership overruled the committee and criticized its reviewer, biostatistician Michael Elashoff. The review of oseltamivir, which was also in approval process at that time, was taken away from him, and reassigned to someone else (Cohen & Carter, 2010). In the EU, experts who provided opinions during the EMEA licensing process for oseltamivir in 1999, had financial connections with Roche, the drug maker (ibid, 2010).

2.2. The Revolving Door

Another major problem related to the COLs is the "revolving door" – a free movement of key employees between regulators and drug companies (Goldacre, 2013). Officials at government regulators may see working for the government as a stepping stone to takes a lucrative position at a drug company. For example, in January 2010, a year after leaving as director of CDC – an agency charged with overseeing vaccines and drug companies, Dr. Julie Gerberding took a position as president of Merck Vaccines. During her tenure as CDC director from 2002 to 2008, Dr. Gerberding supported studies that concluded no link between vaccines and neurological disorders could be found (DeLong, 2012). In January 2011, Elias Zerhouni, former director of the NIH — one of the world's foremost medical research centers, and an agency of the U.S. Department of Health and Human Services — became the president of Sanofi-Aventis' research & Development, covering Medicines and Vaccines (Sanofi, 2010). This frequently exchange of personnel can create a further problem – what if those public officials, while still in post, are thinking on their future at a pharmaceutical company? It is possible that they might be reluctant to make decisions that would alienate a potential future employer (Goldacre, 2013). And While studies these officials do while still working for the government agency may be good analyses, the COI regarding research emphasis or conclusion is unavoidable when they move to the industry that they previously regulated (DeLong, 2012).

Similarly to regulator employees, it was claimed that scientific and medical experts advising the agencies and sitting in their boards often operate with a conflict of interest. For instance, Lurie et al. (2006) found that conflicts of interest are common within FDA drug panels: in 2001-2004, a financial conflict of interest with the affected company was had by one or more panel members in 73% of the 221 drug reviews conducted by the FDA's 16 advisory committees. In a survey done among 997 scientists working at the FDA, 61 percent said they knew of cases where "Department of Health and Human Services or FDA political appointees have inappropriately injected themselves into FDA derterminations or actions". 18.4% said that they themselves "have been asked, for nonscientific reasons, to inappropriately exclude or alter technical information or their cinclusions in an FDA scientific document" (Fromer, 2006).

2.3. Possible Solutions

Goldacre (2013) uses the term "regulatory capture" to describe the process whereby health regulators end up promoting the interests of the industry they were supposed to monitor, at the expense of the public's interest. Ferner (2005) calls the health authorities "David", and argues that they stand very little chance of triumphing over the pharmaceutical "Goliath", as they have no resources to assure their independence. But is that regulatory failure indeed doomed? How, if at all, can conflicts of interest be prevented? There are no easy solutions.

DeLong (2012) suggests closing the revolving door between regulators and drug manufacturers, so that officials could not use public service as a stepping stone to lucrative positions in private industries. Furthermore, she demands that any person in a vaccine policymaking position or any member of a vaccine advisory committee could have no past funding or salary from a vaccine manufacturer, nor should they own stock in a vaccine company. But finding qualified vaccine experts who have no past ties to pharmaceutical companies can be very difficult (Drazen & Curfman, 2002). In order to succeed in the implementation of such policy, or achieve at least a partial success, the implementation process must be long-term and each step should be considered carefully. For example, as a first step, DeLong suggests extending from one to five years the waiting period for policymakers before they can accept a position in an industry they regulated. In the same way, the prohibition of past funding could be phased in by setting caps on the amount a policymaker received in the past, and lowering the caps over time, until ultimately reaching zero (DeLong, 2012).

To ensure a balanced budgetary allocation, Shah (2011) suggests expanding private sector involvement to include companies whose financial interests directly align with those of global health. For example, the fight against malaria could include insurance companies and tourism operators who will gain long-term profits from healthier customers and less fearful tourists, and the battle against NCDs could enlist the participation of local farmers and ranchers whose food will grow more nutritious and thus sold to more people. Recruiting private companies like these, with health-aligned business interests, could create a wider base of private sector donors supporting the WHO, and help re-establish its authority over the global health agenda.

3. PRESS MEETINGS DURING H1N1 OUTBREAK

3.1. Introduction

The purpose of this study was to examine the communications that occurred between two central health authorities – the World Health Organization (WHO) and the Center for Disease Control and Prevention (CDC), and the media, during the 2009 outbreak of the H1N1 influenza virus. The virtual press briefings held by both organizations during the outbreak and published by them provided an opportunity to examine the media's response during the outbreak, the different issues that the journalists focused on and asked about, and the ways in which they related to important issues, such as the decision to declare the H1N1 as a pandemic; the decision to produce vaccines in an accelerated process; and transparency regarding possible conflicts of interests and the decision making process.

3.2. Methods

We analyzed 26 transcripts of virtual press conferences held by the WHO that took place between May 5, 2009 and August 10, 2010, as well as 53 transcripts of virtual press conferences, held by the CDC that took place between April 23, 2009 and March 29, 2010. The transcripts documented the virtual meetings between the WHO and CDC representatives, and Health journalists from media outlets around the world.

3.2.1. Analysis

First, we conducted a preliminary analysis of the transcripts, to examine who were the participants - both from the WHO and the CDC, and from the media; what was the role of the WHO and CDC representatives in their organization; and which media outlet did each of the journalists represent.

We divided the transcripts the WHO's into 3 major periods: 1. From May 5, 2009 (the first transcript found) to June 9, 2009 (the last briefing before the declaration of Phase 6) – 9 transcripts; 2. From June 11, 2009

(the declaration of Phase 6) to December 17, 2009 (the last briefing before the declaration of the end of Phase 6); 3. August 10, 2010 (the declaration of the end of Phase 6).

The CDC's transcripts were divided into 2 major periods: 1. From April 23, 2009 (the first transcript found) to June 4, 2009 (the last briefing before the declaration of Phase 6) – 26 transcripts; 2. From June 11, 2009 (the declaration of Phase 6) to March 29, 2010 – 27 transcripts.

This division helped us to gain a better understanding of the narratives and the dynamics between the participants, in the context of each period. Then, we qualitatively analyzed the transcripts in each period, using thematic and rhetorical analysis to examine the questions asked by the journalists.

The thematic analysis was conducted by dividing the questions in each transcript into 2 categories:

(1) Citation of the question; (2) Summary of the question.

Through This latter category, we further divided the 5 main themes into sub-themes we found, that repeated in the texts:

1. **Down play the disease.**
2. **Hyping the disease.**
3. **Transparency -** in this theme we found 3 main sub-themes:

   a. Transparency regarding possible conflicts of interests; b. Transparency regarding the decision making process; c. Transparency on the part of countries.
4. **Suspicions regarding the organizations' competence**
5. **Suspicions regarding the manufacturing of the new vaccines and anti-viral drugs**

Finally, a rhetorical analysis was done to further identify themes that repeated in the discourse. The rhetoric analysis was conducted by searching for prevalent key words that repeated in the texts, and examining the context in which they were said, in order to find out how the journalists referred to the outbreak and the measures taken to handle it.

3.3. Findings

3.3.1. Preliminary Analysis

Participants of the press conferences included representatives of the WHO and the CDC, who conducted the press briefings, and journalists from media outlets around the world. WHO's representatives included a spokesperson and a senior professional member at the organization, such as the Medical officer in the Global Influenza Programme; Special Adviser to the Director-General etc. (In one case – the June 11, 2009 briefing

– the press conference was held by three senior members - Dr. Margaret Chan, the Director-General of the WHO; Dr Keiji Fukuda, Assistant Director-General ad Interim for Health Security and Environment at WHO; and Dr Marie-Paule Kieny, Director of the Initiative for Vaccine Research at WHO Headquarters. In another case – the final press conference, the briefing was held by two senior members – Dr. Chan and Dr Fukuda).

CDC 's representatives included a spokesperson and a senior professional member at the organization, such as the Director of CDCs Influenza Division. The journalists were from media outlets around the world, including popular media and scientific journals, such as BMJ and Science.

3.3.2. Analysis

Down Play the Disease

A central theme which is prominent in the journalists' questions at the press conferences held both by the WHO and by the CDC until the declaration of Phase 6 by the WHO on June 9 is "Down play the disease". As the following quotes illustrate, the journalists were anxious to see the H1N1 declared as a pandemic, and expressed distrust and suspicion regarding to what they perceived as an improper delay in the declaration:

> *"At the beginning of your remarks you said that in Australia a great deal of activity is being seen in Victoria at the community level.* ***Why then has the WHO not declared a pandemic, is there any doubt in your mind that this is a pandemic at this point?"*** (WHO, June 9, 2009).

Furthermore, some of the journalists have argued explicitly that the organizations were "down playing" the disease in response to pressures from politicians:

> *"…it is true that some politicians are trying to play down the disease at this moment. Is this a wise thing to do at this point?" (WHO, May 11, 2009).*
>
> *"I wanted to follow up on David Brown's question. He asked, I thought sensibly, why not bite the bullet and raise it to level 6 if it meets level 6. The response was: what is the gain, this could be the panic, this could be the cynicism, but isn't that the other danger is that if WHO changes its rules in the middle of the game, and appears to bend with the political pressure, that you create cynicism as well.* ***If it looks like WHO will bend with the political pressure then it might do it with another public health crisis and there is a loss of confidence in WHO****" (WHO, May 26, 2009).*
>
> *"Regarding the W.H.O. announcement, there was speculation or even expectation that might happen for weeks and weeks and weeks.* ***Now that it's finally happened, was that delay in some way, beneficial in terms of the public understanding that it wasn't as severe as it might have been at the beginning?*** *Can you comment on that?" (CDC, June 11, 2009).*

Hyping the Disease

While the journalists were concerned about downplaying the disease, they rarely related to the possibility of exaggerating the disease and moving too fast towards the declaration of stage 6. Such concerns are only found in 4 instances during May 9-June 9, 2009 in the WHO's press conferences. For example:

> *"**Do you [unintelligible] that the news about the risk of the spread of the disease and also about the risk about the severity of the disease has been exaggerated?** Secondly, is there a risk that WHO has raised expectations so high that some countries might play the spread of the disease down?" (WHO, May 11, 2009).*
>
> *"**Could you comment on what US Health Secretary, Kathleen Sebelius said, that the virus appears not to be as strong as feared**. Do you agree?" (WHO, May 5, 2009).*

After the declaration, it seems that the journalists welcomed the step and expressed no suspicion or distrust over it. In fact, starting from June 9, 2009 up to the final press conference in which the WHO declared that the pandemic was over, we found only two cases in the WHO's press conferences, in which journalists have questioned the step:

> *"I think you confirmed that the death toll of the H1N1 2009 is over 10,000. My question is what is the assessment of this number? **I think some people are questioning that it will be much fewer than the seasonal influenza so what is your view of the fatality rate?**" (WHO, December 17, 2009).*
>
> *"I am wondering if WHO has given any thought **to when it would feel safe to declare the pandemic over.** What is the mechanism for doing that, and how would you do that, and I ask, because there are certainly people who feel that this has turned out to be much less of a threat to global health than was first thought. In fact CDC has come up with this fatality ratio of 0.018, which people are pointing to suggest this is quite a mild event" (WHO, December 3, 2009).*

Only in less than a handful of cases – two of them in the WHO's last press conference, in which the WHO declared the pandemic was over, and one in a CDC's press conference – the theme of "Hyping the disease" appeared prominently. For example:

> ***"The WHO was accused of hyping the pandemic** and I'm wondering whether this might pose problems for you in the future if as and when a new pandemic arises?" (WHO, **August 10, 2010).***
>
> *"I just wanted to ask Dr Chan, are you still convinced that you made the right call in June of 2009 to declare the pandemic, **in view of the heavy criticism that followed"(** WHO, **August 10, 2010).***
>
> *"Since the number of cases of H1N1 are lower than some had originally feared, **will the initial response to future pandemics be scaled back**, or will what we saw this year as a CDC and national response serve as sort of a blueprint moving forward?" (CDC, February 5, 2010).*

Transparency

Another aspect of suspicious and criticism – transparency regarding issues such as conflicts of interests and the identity of the decision makers almost didn't exist in the journalist's question.

a. Regarding Possible Conflicts of Interests

Not even once has the question of transparency regarding the possible ties between the organizations and the pharmaceutical been raised during the press conferences held until the WHO declared that the pandemic was over. Furthermore, it seems as if the journalists had felt that there was a need to "convince" the industry to manufacture the new vaccine. For example:

> *"It sounds like the vaccine industry really had a question over the severity of the illness and that was something that they were trying to weigh up in order to determine whether they should switch to making a shot for H1N1 this new strain. And now it sound like there is sufficient evidence to show that this is actually more pathogenic than seasonal flu.* ***Is that going to give them enough to sway them to producing a shot*** *for this new virus when they have the seed vaccine available?" (WHO, May 13, 2009).*
>
> *"You've talked about how much better prepared we are since SARS and definitely a lot of money has gone into preparedness, but you face a couple of limiting factors right now. One is that the HHS Secretary hasn't been confirmed and secondly,* ***state and local health departments are facing a real funding crunch in the recession and I'm wondering if you can address those two. What do you need to more effectively do your job and are those limiting you?"*** *(CDC, April 27, 2009).*

It wasn't until the WHO's last press conference, in August 10, 2010, that the journalists had finally asked for transparency regarding the money the WHO received during the outbreak, and even then, it was merely one single question that was raised. There was no follow-up of more critical questions, such as who exactly donated the money and how much was received from each pharmaceutical company involved:

> *"Do you know how much money WHO received specifically to deal with H1N1 over the past year and what it was spent on?"* ***(****WHO, August 10, 2010).*

b. Regarding the Decision Making Process

During the announcement of the pandemic or the many press conferences held by both organizations that followed, the journalists did not even once ask for transparency regarding the decision making process. Only the WHO's last press conference, when the WHO declared the pandemic was over – one journalist required to disclose the names of the committee members that took the decision, and thus, demanded that the WHO would take responsibility for the decision to declare the end of the pandemic (something they haven't done when the pandemic was declared)**:**

"When you talk about the revision of the regulations, ***are you talking also about making it public, the names and the people that are actually taking part on the committee that took this decision today?*** *Basically my question is whether the names of the people in the committee that took the decision today, will they be, from now on, publicized, or they will still be kept as a secret?"* ***(****WHO, August 10, 2010).*

c. Transparency on the Part of Countries

Another aspect related to transparency raised by the journalists during press conferences held by both organizations was the claim or suspicion that some of the countries did not report properly to the WHO on the spread of the outbreak. For example:

"And secondly am wondering if there is any concern at WHO that there may be community spread happening in certain countries in Europe, like say Britain, that are not reporting, are not testing for it. Do you think you are getting accurate information from these countries?" (WHO, June 9, 2009).

"There was a story out of Beijing this morning by medical experts suggesting that China may have had more H1 flu deaths than have been officially reported. I wondered if you were aware of these sort of reports and whether you are convinced that authorities are in fact checking and recording correctly the causes of deaths, in other words, that they are reporting accurately to WHO" (WHO, November 19, 2009).

*"****There are some basic facts here have been very hard to get****. ****Most important is the epidemic curve in Mexico****. Is that -- the outbreak there ongoing, or is it over and they're simply counting up the cases? If it's ongoing, are the numbers of cases being -- is there a rising curve, is it a falling curve, when was the last onset of a fatal illness? Or do you not know the answer to those questions." (CDC, April 25, 2009)****.***

*"****There's been some concern that our reliance on vaccine manufacturers in foreign countries leave us vulnerable*** *– that they would supply their own countries in the event of a pandemic, ongoing pandemic, and that supplies that we counted on from them might not come to us, are you concerned about that?" (CDC, July 17, 2009).*

Suspicions Regarding the Organizations Competence

Another issue the journalists demonstrated concerns about was the WHO's competence. Alongside their suspicions that some of the countries might have not been transparent regarding the spread of the outbreak, they also suspected that the organizations did not work enough to monitor the states, as well as the clinical trials done by the pharmaceutical companies. For example:

"The WHO still has about 15 million vaccines which need to be delivered, mostly to Third World countries, not to mention there were 12 million vaccines delivered to Bangladesh ten days ago; ***what does this say about the WHO's response to this pandemic that those at the highest risk of infection received their vaccine after the threat of the pandemic has abated?" (****WHO, August 10, 2010).*

"When you mentioned the names of the countries that are doing research you didn't mention Switzerland. But Novartis announced that they have begun clinical trials. Is that from the US arm, or is it not something WHO has been told about? And what is the possibility there are a lot more trials going on that maybe the WHO is not aware about?" (WHO, August 6, 2010).

"I was looking for an update on lab analysis that CDC had done. Yesterday, you said 14 samples tested from Mexico, 7 positive. ***Is that still the count?*** *Of those that have been positive, any of those -- were any of those deaths? Parts two of that question, you were looking at context family members of the eight people in the U.S.,* ***have some of those tests come back negative then?"*** *(CDC, April 25, 2009).*

"The test that you do at CDC, as I understand it, depends on reagents that other people don't have. ***What are those reagents and why are they not distributed widely to Mexico and to state health departments and county health departments?****" (CDC, April 25, 2009).*

*"****I have talked to a couple of infectious disease experts around the country and some of them have wondered if CDC plans to issue guidelines*** *to hospitals for treating flu-like infections presenting in ERs." (CDC, April 26, 2009).*

"Have you done any tests to see whether there's any antigenic cross-activity between this virus and currently circulating human H1N1? ***I can't believe you haven't done a human inhibition test, for example, it's pretty straightforward.*** *Do you have any idea whether this thing shares antigenic reactivity in common with H1N1?" (CDC, April 26, 2009).*

"Has anyone had a chance to look back, you mentioned San Diego, ***has anyone looked further back to see whether the virus was around weeks and months ago in this country****?" (CDC, April 27, 2009).*

"This is a follow-up to that question for Mike bell. The MMWR this week has a paragraph, additional messages aimed at reinforcing controls are needed that ***implies that the CDC has found there have been real failures in infection control****.* ***I guess you sort of outlined them, failure to identify patients when they first come in, failure to make sure the health care workers don't come to work sick****. Is the CDC going to do more than basically print this sentence and make recommendations? Are you going to do anything to press states to enforce regulations, press for new policies from hospitals, press for an absolute policy that sick patients be identified, something like that? How tough can it get?" (CDC, June 11, 2009).*

"Are you doing any sero surveys in parts of the U.S. to try to get a better handle on how many people have been infected in this wave?" (CDC, June 26, 2009).

Suspicions Regarding the Manufacturing of the New Vaccines and Anti-Viral Drugs

During the many press conferences held by both organizations until the WHO declared the end of the pandemic, the journalists were clearly interested in speeding up **the development and the production** of the new vaccine. For example:

> *"I understand that vaccine has some seed stocks to pile up and then full scale manufacturing.* ***Is there a day, a week in time that WHO has set to make the decision whether to go to full scale manufacturing?"*** *(WHO, May 13, 2009).*
>
> *"**I'm kind of curious, what's the likelihood we wouldn't have a vaccine in the U.S. until later in the season than you would like?** (CDC, May 20, 2009)*
>
> *"Can you tell us a little bit about the testing that was done and **when we are likely to see the first vaccine come off the production line?** And who might be eligible to get this vaccine?" (CDC, May, 28, 2009).*
>
> This interest was even more prominent after the declaration of phase 6:
>
> *"**When would you expect the first doses of pandemic vaccine from cell culture to arrive?**" (WHO, July 13, 2009)*
>
> *"I was wondering if you could give us an update on the availability of vaccines going out to countries.* ***Yesterday CDC experts stressed that availability at the end of October in the United States was a fraction of what they had predicted early this year. So how far behind the initial projections are companies in the production cycle of the vaccines?**" (WHO, 5 November 2009).*
>
> *"I was also wondering just on the vaccine question, **I know we talked about it a lot, but is it still a question of concern about whether we're even going to have a vaccine available** and through all the testing and clinical trials by the time flu season comes around? (CDC, June 11, 2009).*

At the same time, the journalists also expressed **concerns** regarding safety issues, such as side effects and risks, and the potential problematic implications that might result from the accelerated production. However, these concerns were not shown until the declaration of phase 6.

> *"I wonder with the accelerated safety tests that will be necessary, how many subjects will you expect to have tested and **how can experts draw conclusions about safety from these tests when the vaccine has put into a hundreds of millions of people**" (WHO, July, 13 2009).*
>
> *"Could I ask you to just repeat very briefly the European regulations and **how the Europeans are going to be testing the new vaccines**" (WHO, August 6, 2009).*

A central safety issue related to the vaccine the journalists were suspicious about was the issue of adjuvants that was added to some of the H1N1 vaccines. They presented evidence on potential safety problems related to adjuvants, and also noted that the US has not approved the adjuvanted vaccines and Switzerland has limited the approval. For example:

"I would like to get some information about adjuvants and children… I don't think that there is much evidence at all about safety of adjuvants in that group … Are there any other vaccines – not influenza vaccines – ***but marketed vaccines with these kind of adjuvants that children receive now and that might give us a sense of whether or not they are safe to use in children?" (****WHO, July, 13 2009).*

"…we see from the wire from ASP, in Geneva, exactly where you are, ***Switzerland decided that the adjuvant AS03, used by GSK, is not approved in the vaccine pandemerics for pregnant women, children aged 18 and less, and adults of more than 60 years old. And in the US, it's the same thing. The adjuvant vaccine has not been approved.*** *So I suppose you looked when you did your survey into the experience of those countries and their expertise so could expand more on the examination you have done on this question?" (WHO, October 20, 2009).*

"Can you talk a little bit more about how effective the seasonal flu vaccine is and can you speak to some of the popular arguments against getting one such as the dangers and the ingredients such as mercury, other risks and the strains in the vaccine not matching the strains that are circulating?" (CDC, May 21, 2009).

Other issues related to possible adverse effects were Guillain-Barré Syndrome (a disorder affecting the peripheral nervous system) and anaphylactic shock:

*"****With reference to anaphylactic shock in Canada.*** *Is the substance that triggered the allergies benn identified yet?" (WHO, November 26, 2009).*

"Dr Kieny, you said earlier that you do not expect safety issues to arise with the pandemic vaccine and tests but ***do you think that there is less risk of Guillain-Barre syndrome with this new swine flu vaccine than there was in 1976 and why?****" (July 13, 2009).*

*"****I would like to know how similar the vaccines which are now under development are to the vaccine from the 1976 vaccine in the US which caused Guillain-Barré Syndrome problems****" (WHO, 6 August 2009).*

3.4. Summary

During the many press conferences held by both the WHO and the CDC, the journalists raised questions indicating distrust quite often. Nonetheless, the most burning issues – i.e., "the pandemic that never was"; possible conflicts of interests between the organizations and the pharmaceutical companies; and transparency on the decision making process, were absent from the discourse.

The most prominent issue absent was "the pandemic that never was". It seems that the journalists, both at the WHO and the CDC briefings, were so anxious to see the H1N1 declared as a pandemic, that they rarely related to the possibility of exaggerating the disease and moving too fast towards the declaration. Instead, they expressed distrust and suspicion regarding to what they perceived as an improper delay in the

declaration. They asked frequently for information on the disease, its symptoms, the patients, and some of them even argued explicitly that the organizations were "down playing" the disease.

Similarly, during the press conferences held by both organizations until the WHO declared the end of the pandemic, the journalists did not relate to the potential problematic implications that might result from the accelerated production of the vaccines, meaning safety and efficacy issues. Instead, the journalists were clearly interested in speeding up the development and the production of the new vaccine. Questions about the vaccine's safety and efficiency were raised only after the vaccines were in the market, and even then, not often.

Another aspect of suspicious and criticism – transparency regarding issues such as conflicts of interests and the decision making process almost didn't exist in the journalist's questions. Not even once has the question of transparency regarding the possible ties between the organizations and the pharmaceutical been raised during the press conferences held by both the CDC and the WHO until the WHO declared that the pandemic was over. Furthermore, it seems as if the journalists had felt that there was a need to "convince" the industry to manufacture the new vaccine. Only in the WHO's last press conference, in August 10, 2010, the journalists had finally asked for transparency regarding the money the WHO received during the outbreak, and required to disclose the names of the committee members that took the decision – but even then, it was merely one single question that was raised on each subject.

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